MajesTEC-3: *Post hoc* analysis of OS, progression, and NRM with Tec-Dara in RRMM

N = 587

Phase III MajesTEC-3 (NCT05083169)

Primary endpoint: PFS. **Key secondary endpoints:** ≥CR, ORR, MRD negativity (10^{-5}), OS, MySIm-Q Total Symptom Score. **Eligibility:** RRMM with 1–3 prior LoT including a PI and lenalidomide; ECOG PS 0–2.

TRIAL DESIGN

Tec-Dara (n = 291) vs **DPd/DVd** (n = 296)

1:1 randomization

Teclistamab + Daratumumab	Daratumumab + Pomalidomide/bortezomib + Dexamethasone
SC dosing following daratumumab schedule. Steroid-sparing schedule after Cycle 1 Day 8 and monthly dosing after 6 cycles.	Administered per the approved dosing schedules.

Primary analysis

PFS and OS were significantly improved with Tec–Dara vs DPd/DVd.

36-month PFS

83.4% vs 29.7%

HR, 0.17; 95% CI, 0.12–0.23; p < 0.0001

36-month OS

83.3% vs 65.0%

HR, 0.46; 95% CI, 0.32–0.65; p < 0.0001

Post hoc OS, progression, and NRM analysis

This *post hoc* competing-risk analysis evaluated the contribution of disease progression and NRM to the observed OS in MajesTEC-3.

COMPETING-RISK ANALYSIS

Tec-Dara | DPd/DVd

Cumulative incidence of progression (CIP)
(with NRM as a competing risk)*

8.7% | 36-month CIP rate | 62.1%

sHR: 0.10 (95% CI, 0.07–0.16; nominal p < 0.0001)

Disease progression
24 patients (18 with subsequent death)
vs 171 patients (72 with subsequent death)

NRM
(with CIP as a competing risk)†

10.2% | 36-month NRM rate | 9.0%

sHR: 1.16 (95% CI, 0.69–1.98; nominal p = 0.5668)

Death without progression
28 patients vs 26 patients

Causes of NRM

NRM was primarily due to AEs in both groups

68% | AE-related NRM | 62%

n = 19/28 | n = 16/26

Leading causes of AE-related NRM

	Tec-Dara	DPd/DVd
Infections and infestations	63%	25%
General disorders/admin site conditions	11%	25%
Respiratory disorders	11%	19%
Nervous system disorders	5%	13%

TIME-STRATIFIED COX ANALYSIS OF OS

Deaths within the first 10 months were comparable between treatment groups.

Beyond 10 months, OS favored **Tec-Dara** (HR, 0.22; 95% CI, 0.13–0.38), corresponding to a 78% reduction in the risk of death.

Tec-Dara significantly improved PFS and OS vs DPd/DVd in patients with RRMM treated with 1–3 prior LoT. This analysis suggests that the observed OS benefit is driven by a reduction in disease progression, the leading cause of mortality in RRMM, while NRM remained comparable over time.

AE, adverse event; CI, confidence interval; CIP, cumulative incidence of progression; CR, complete response; Dara, daratumumab; DPd, daratumumab + pomalidomide + dexamethasone; DVd, daratumumab + bortezomib + dexamethasone; ECOG PS, Eastern Cooperative Oncology Group performance status; HR, hazard ratio; LoT, lines of therapy; MRD, minimal residual disease; NRM, non-relapse mortality; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; PI, proteasome inhibitor; RRMM, relapsed/refractory multiple myeloma; SC, subcutaneous; sHR, subdistribution hazard ratio; Tec, teclistamab.

*Rate of disease progression when accounting for the fact that patients who die prior to progression cannot go on to experience disease progression.

†Rate of dying from non-relapse causes when taking into consideration that patients who experience disease progression first are no longer “at-risk” of NRM.

Costa LJ. Oral Abstract #OA-49. 23rd IMS Annual Meeting and Exposition; Sep 23–26, 2026; Glasgow, UK.

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